UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO

DONALD PALIOTTI	:	Assigned To: Honorable Judge David A. Katz
Plaintiff,	:	
	:	**MDL DOCKET NO.: 1:10-md-2197**
	:	
	:	**COMPLAINT**
v.	:	**AND JURY DEMAND**
	:	
DEPUY ORTHOPAEDICS, INC. and JOHNSON & JOHNSON,	:	**Civil Action No.:**
	:	
	:	
Defendants.	:	

Plaintiff DONALD PALIOTTI, by and through his attorneys PARKER WAICHMAN ALONSO, LLP, hereby brings this complaint against Defendants DEPUY ORTHOPAEDICS, INC. and JOHNSON & JOHNSON, and allege as follows, upon information and belief:

NATURE OF THE ACTION

1. This is an action to recover damages for personal injuries suffered by the Plaintiff as a direct and proximate result of Defendants' negligent and wrongful conduct in connection with the development, testing, assembling, manufacture, packaging, labeling, preparing, distribution, marketing, supplying, and/or selling the defective product sold under the name "ASR XL Acetablular System."

2. The DePuy ASR XL Acetabular System hip replacement device was recently the subject of a national recall through an announcement issued by Defendant DePuy on or about August 24, 2010, which indicated that the device had an unacceptable failure rate resulting in revision surgery in 13% of patients within 5 years.

JURISDICTION AND VENUE

3. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy as to the Plaintiff exceeds $75,000.00, exclusive of interest and costs, and because Defendants are incorporated and have their principal places of business in states other than the state in which the named Plaintiff resides.

4. Venue of this case is appropriate in the United States District Court for the Eastern District of Virginia. Plaintiff states that, but for the order permitting direct filing into the Northern District of Ohio pursuant to Case Management Order # 2, plaintiff would have filed in the United States District Court for the Eastern District of Virginia. Therefore, plaintiff respectfully requests that at the time of transfer of this action back to the trial court for further proceedings that this case be transferred to the above referenced District Court.

PLAINTIFF

5. Plaintiff DONALD PALIOTTI is a natural person and a citizen of the County of Virginia Beach City, Commonwealth of Virginia.

DEFENDANTS

6. Defendant DEPUY ORTHOPAEDICS, INC. ("DePuy") is an Indiana Corporation with its principal place of business at 700 Orthopaedic Drive, Warsaw, Indiana 46581. Defendant DePuy is a resident and citizen of Indiana.

7. At all times material hereto, Defendant DePuy developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, and/or sold the defective product sold under the name the "ASR XL Acetabular System," either directly or indirectly, to members of the general public throughout the United States.

8. Defendant JOHNSON & JOHNSON ("J&J") is a New Jersey Corporation with its principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933. Defendant J&J is a resident and citizen of New Jersey.

9. At all times material hereto, Defendant J&J, as the parent company of DePuy developed, tested, assembled, manufactured, packaged, labeled, prepared, distributed, marketed, supplied, and/or sold the defective product sold under the name the "ASR XL Acetabular System," either directly or indirectly, to members of the general public throughout the United States.

FACTUAL ALLEGATIONS

10. Defendants' defective device was placed into the stream of interstate commerce and was implanted in Plaintiff on or about November 10, 2008.

11. As a direct and proximate result of Defendants placing the defective product into the stream of commerce, Plaintiff Donald Paliotti has suffered and continues to suffer both injuries and damages, including but not limited to: past, present and future physical and mental pain and suffering; and past, present and future medical, hospital, rehabilitative and pharmaceutical expenses, lost wages, and other related damages.

12. Defendants received FDA approval to sell their ASR XL Acetabular system in the United States.

13. The ASR XL Acetabular system containing a metal-on-metal acetabular bearing couple is indicated for patients requiring primary total hip arthroplasty or replacement due to painful disabling joint disease of the hip resulting from non-inflammatory degenerative arthritis.

14. The ASR XL Acetabular system is an artificial hip replacement device consisting of three components: the femoral stem, which is inserted into the femur, the femoral head (or ball), and the metal acetabular cup (or socket), inside of which the femoral ball sits.

15. At all times material hereto, the acetabular hip implant device used in Plaintiff Donald Paliotti's surgery was designed, manufactured, marketed, retailed, distributed, and/or supplied by Defendants.

16. After the implantation of the defective device, Plaintiff Donald Paliotti began experiencing significant pain, clicking and popping sensations, constant irritation, and discomfort in the area of his defective device.

17. On or about September 1, 2010, Plaintiff Donald Paliotti received notification from his treating orthopaedic surgeon that the hip replacement implant he received in November of 2008 had been recalled by Depuy.

18. On or about January 5, 2011, Plaintiff Donald Paliotti underwent a revision of his defective hip implant.

THE RECALL

19. Defendants' ASR XL Acetabular System is a prosthetic orthopaedic device used in patients in need of a hip replacement.

20. The ASR XL Acetabular system is an artificial hip replacement device consisting of three components: the femoral stem, which is inserted into the femur, the femoral head (or ball), and the metal acetabular cup (or socket), inside of which the femoral ball sits.

21. In or about March 2010, Defendant DePuy issued a Field Safety Notice regarding its ASR hip replacement system. The Field Safety Notice Provided new data which demonstrated that the ASR system had a higher than expected failure rate.

22. On or about August 24, 2010, Defendant DePuy issued a nationwide recall notice for all of its ASR XL Acetabular System. The recall was based on data demonstrating a higher than expected revision surgery rate in 13% of patients within five years.

23. DePuy's recall notice states that reasons for the higher than expected revisions of the metal-on-metal system included component loosening, component mal-alignment, infections, fracture of the bone, dislocation, metal sensitivity and pain.

24. In its nationwide recall, DePuy instructed physicians to cease implanting the device. Further, DePuy advised physicians to monitor the medical conditions of patients with the device through specific blood tests, radiographic tests and other diagnostic means. Further, DePuy advised physicians that revision surgery would be necessary in some cases, and that patients must receive revision surgery as soon as problems were detected in order to avoid further complications and injury.

FEDERAL REQUIREMENTS

25. Federal regulation states that "recall means a firm's removal or correction of a marketed product that the Food and Drug Administration considers to be in violation of the laws it administers and against which the agency would initiate legal action, *e.g.* seizure." *See* 21 CFR §7.3(g).

26. Federal regulation states that "recall classification means the numerical designation, *i.e.*, I, II or III, assigned by the Food and Drug Administration to a particular product recall to indicate the relative degree of health hazard presented by the product being recalled." *See* 21 CFR §7.3(m).

27. Federal regulation states that "class II is a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote." *See* 21 CFR §7.3(m).

28. The classification of the product withdrawals and corrections of the Defendant's devices (described above) as Class II Recalls by the FDA confirms by definition that the devices were in violation of federal law and that initiation of legal action or seizure would be indicated for these devices.

29. Pursuant to federal law, a device is deemed to be adulterated if, among other things, it fails to meet established performance standards, or if the methods, facilities or controls used for its manufacture, packing, storage or installation are not in conformity with federal requirements. *See* 21 U.S.C. §351.

30. Pursuant to federal law, a device is deemed to be misbranded if, among other things, its labeling is false or misleading in any particular manner, or if it is dangerous to health when used in the manner prescribed, recommended or suggested in the labeling thereof. *See* 21 U.S.C. §352.

31. Pursuant to federal law, manufacturers are required to comply with FDA regulation of medical devices, including FDA requirements for records and reports, in order to prohibit introduction of medical devices that are adulterated or misbranded, and to assure the safety and effectiveness of medical devices. In particular, manufacturers must keep records and make reports if any medical device that may have caused or contributed to death or serious injury, or if the device has malfunctioned in a manner likely to cause or contribute to death or serious injury. Federal law also mandates that the FDA establish regulations requiring a manufacturer of a medical device to report promptly to FDA any correction or removal of a

device undertaken to reduce a risk to health posed by the device, or to remedy a violation of federal law by which a device may present a risk to health. *See* 21 U.S.C. §360(i).

32. Pursuant to federal law, the Secretary of Health and Human Services may prescribe regulations requiring that the methods used in, and that facilities and controls used for, the manufacture, pre-production design validation (including a process to assess the performance of a device but not including an evaluation of the safety or effectiveness of a device), packaging, storage, and installation of a device conform to current good manufacturing proactive, as prescribed in such regulations, to assure that the device will be safe and effective and otherwise in compliance with federal law. *See* 21. U.S.C §360j(f).

33. Pursuant to federal regulation, adverse events associated with a medical device must be reported to FDA within thirty (30) days after the manufacturer becomes aware that a device may have caused or contributed to death or serious injury, or that a device has malfunctioned and would be likely to cause or contribute to death or serious injury if the malfunction was to recur. Such reports must contain all information reasonably known to the manufacturer, including any information that can be obtained by analysis, testing, or other evaluation of the device, and any information in the manufacturer's possession. In addition, manufacturers are responsible for conducting an investigation of each adverse event, and must evaluate the cause of the adverse event. *See* 21 CFR §803.50.

34. Pursuant to federal regulation, manufacturers of medical devices must also describe in every individual adverse event report whether remedial action was taken in regard to the adverse event, and whether the remedial action was reported to FDA as a removal or correction of the device. *See* 21 CFR §803.52.

35. Pursuant to federal regulation, manufacturers must report to FDA within five (5) business days after becoming aware of any reportable Medical Device Reporting (MDR) event or events, including a trend analysis that necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health. *See* 21 CFR §803.53.

36. Pursuant to federal regulation, device manufacturers must report promptly to FDA any device corrections and removals, and maintain records of device corrections and removals. FDA regulations require submission of a written report within ten (10) working days of any correction or removal of a device initiated by the manufacturer to reduce a risk to health posed by the device, or to remedy a violation of the Act caused by the device, which may present a risk to health. The written submission must contain, among other things, a description of the event giving rise to the information reported and the corrective or removal actions taken, and any illness or injuries that have occurred with use of the device, including reference to any device report numbers. Manufacturers must also indicate the total number of devices manufactured or distributed which are subject to the correction or removal, and provide a copy of all communications regarding the correction or removal. *See* 21 CFR §806.

37. Pursuant to federal regulation, manufacturers must comply with specific quality system requirements promulgated by FDA. These regulations require manufacturers to meet design control requirements, including but not limited to conducting design validation to ensure that devices conform to defined user needs and intended uses. Manufacturers must also meet quality standards in manufacture and production. Manufacturers must establish and maintain procedures for implementing corrective actions and preventive actions, and investigate the cause of nonconforming products and take corrective action to prevent recurrence. Manufacturers are also required to review and evaluate all complaints and determine whether an investigation is

necessary. Manufacturers are also required to use statistical techniques where necessary to evaluate product performance. *See* 21 CFR §820.

38. The regulations requiring conformance to good manufacturing practices are set forth in 21 CFR §820 *et seq.* As explained in the Federal Register, because the Current Good Manufacturing Practice (CGMP) regulations must apply to a variety of medical devices, the regulations do not prescribe the details for how a manufacturer must produce a device. Rather, the quality system regulations provide a framework of basic requirements for each manufacturer to use in establishing a quality system appropriate to the devices designed and manufactured, and the manufacturing processes employed. Manufacturers must adopt current and effective methods and procedures for each device they design and manufacture to comply with and implement the basic requirements set forth in the quality system regulations.

39. Pursuant to 21 CFR §820.1(c), the failure to comply with any applicable provision in Part 820 renders a device adulterated under section 501(h) of the Federal Food Drug & Cosmetic Act ("the Act") (21 U.S.C. § 351).

40. Pursuant to 21 CFR §820.5, each manufacturer shall establish and maintain a quality system that is appropriate for the specific medical device designed or manufactured. "Quality system" means the organization's structure, responsibilities, procedures, processes, and resources for implementing quality management. *See* 21 CFR §820.3(v).

41. Pursuant to 21 CFR §820.22, each manufacturer shall establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system.

42. Pursuant to 21 CFR §820.30(a), each manufacturer shall establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met.

43. Pursuant to 21 CFR §820.30(d), each manufacturer shall establish and maintain procedures for defining and documenting design output in terms that allow an adequate evaluation of conformance to design input requirements.

44. Pursuant to 21 CFR §820.30(e), each manufacturer shall establish and maintain procedures to ensure that formal documented reviews of the design results are planned and conducted at appropriate stages of the device's design development.

45. Pursuant to 21 CFR §820.30(f), each manufacturer shall establish and maintain procedures for verifying the device design to confirm that the device design output meets the design input requirements.

46. Pursuant to 21 CFR §820.30(g), each manufacturer shall establish and maintain procedures for validating the device design. Design validation shall be performed under defined operating conditions on initial production units, lots, or batches, or their equivalents. Design validations shall ensure that devices conform to defined user needs and intended uses and shall include testing of production units under actual or simulated use conditions.

47. Pursuant to 21 CFR §820.30(h), each manufacturer shall establish and maintain procedures to ensure that the device design is correctly translated into production specifications.

48. Pursuant to 21 CFR §820.30(i), each manufacturer shall establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation.

49. Pursuant to 21 CFR §820.70(a), each manufacturer shall develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications. Where deviations from device specifications could occur as a result of the manufacturing process, the manufacturer shall establish and maintain process control procedures that describe any process controls necessary to ensure conformance to specifications. Such process controls shall include:

a. Documented instructions, standard operating procedures (SOP's), and methods that define and control the manner of production;

b. Monitoring and control of process parameters and component and device characteristics during production;

c. Compliance with specified reference standards or codes;

d. The approval of processes and process equipment; and

e. Criteria for workmanship which shall be expressed in documented standards or by means of identified and approved representative samples.

50. Pursuant to 21 CFR §820.70(b), each manufacturer shall establish and maintain procedures for changes to a specification, method, process, or procedure.

51. Pursuant to 21 CFR §820.70(c), each manufacturer shall establish and maintain procedures to adequately control environmental conditions that could reasonably be expected to have an adverse effect on product quality, including periodic inspection of environmental control system(s) to verify that the system, including necessary equipment, is adequate and functioning properly.

52. Pursuant to 21 CFR §820.70(e), each manufacturer shall establish and maintain procedures to prevent contamination of equipment or product by substances that could reasonably be expected to have an adverse effect on product quality.

53. Pursuant to 21 CFR §820.70(g), each manufacturer shall ensure that all equipment used in the manufacturing process meets specified requirement and is appropriately designed, constructed, placed, and installed to facilitate maintenance, adjustment, cleaning and use.

54. Pursuant to 21 CFR §820.70(h), each manufacturer shall establish and maintain procedures for the use and removal of manufacturing material which could reasonably be expected to have an adverse effect on product quality to ensure that it is removed or limited to an amount that does not adversely effect the device's quality.

55. Pursuant to 21 CFR §820.70(i), when computers or automated data processing systems are used as part of production or the quality system, the manufacturer shall validate compute software for its intended use according to an established protocol.

56. Pursuant to 21 CFR §820.72, each manufacturer shall ensure that all inspection, measuring, and test equipment, including mechanical, automated, or electronic inspection and test equipment, is suitable for its intended purposes and is capable of producing valid results. Each manufacturer shall establish and maintain procedures to ensure that equipment is routinely calibrated, inspected, checked, and maintained.

57. Pursuant to 21 CFR §820.75(a), where the results of a process cannot be fully verified by subsequent inspection and test, the process shall be validated with a high degree of assurance and approved according to established procedures. "Process validation" means establishing by objective evidence that a process consistently produces a result or product meeting its predetermined specifications. *See* 21 CFR §820.3(z)(1).

58. Pursuant to 21 CFR §820.75(b), each manufacturer shall establish and maintain procedures for monitoring and control of process parameters for validated processes to ensure that the specified requirements continue to be met. Each manufacturer shall ensure that validated processes are performed by qualified individuals.

59. Pursuant to 21 CFR §820.90, each manufacturer shall establish and maintain procedures to control product that does not conform to specified requirements.

60. Pursuant to 21 CFR §820.100, each manufacturer shall establish and maintain procedures for implementing corrective and preventive action. The procedures shall include requirements for:

a. Analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problem,

b. Investigating the cause of nonconformities relating to product, processes and the quality system;

c. Identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems;

d. Verifying or validating the corrective and preventative action to ensure that such action is effective and does not adversely affect the finished device;

e. Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems;

f. Ensuring that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such

product or the prevention of such problems; and

g. Submitting relevant information on identified quality problems, as well as corrective and preventative actions, for management review.

DEFENDANTS' ASR XL ACETABULAR SYSTEM IS A 510(k) APPROVED MEDICAL DEVICE

61. Defendants submitted a §510(k) premarket notification and obtained marketing approval for its ASR XL Acetabular System from the FDA under Section 510(k) of the Act. *See* 21 U.S.C. §360 *et seq.*

62. Under the § 510(k) approval process, the FDA determined that Defendants' ASR XL Acetabular System was "substantially equivalent" to devices that have been reclassified in accordance with the provisions of the Act and did not require FDA approval of a pre-market approval application (PMA).

63. Upon information and belief, Defendants' ASR XL Acetabular System is adulterated pursuant to 21 U.S.C. §351 because, among other things, it failed to meet established performance standards, and/or the methods, facilities, or controls used for its manufacture, packing, storage or installation are not in conformity with federal requirements. *See* 21 U.S.C. §351.

64. Upon information and belief, Defendants' ASR XL Acetabular System is misbranded because, among other things, it is dangerous to health when used in the manner prescribed, recommended or suggested in the labeling thereof. *See* 21 U.S.C. §352.

65. Upon information and belief, Defendant's ASR XL Acetabular System is adulterated pursuant to 21 U.S.C. §351 because Defendants failed to establish and maintain CGMP for their ASR XL Acetabular System in accordance with 21 CFR §820 *et seq.*, as set forth above.

66. Upon information and belief, Defendants failed to establish and maintain CGMP with respect to the quality audits, quality testing and process validation for their ASR XL Acetabular System.

67. As a result of Defendants' failure to establish and maintain CGMP as set forth above, Defendants' ASR XL Acetabular System was defective and failed, resulting in injuries to the Plaintiff.

68. If Defendants had complied with the federal requirements regarding CGMP, Defendants' ASR XL Acetabular System would have been manufactured properly such that it would not have resulted in injuries to the Plaintiff.

FIRST CAUSE OF ACTION AS AGAINST DEFENDANTS
(STRICT PRODUCTS LIABILITY - MANUFACTURING DEFECT)

69. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows.

70. Defendants are the manufacturers, designers, distributors, sellers, and/or suppliers of orthopedic devices including the DePuy ASR XL Acetabular System.

71. The ASR XL Acetabular System manufactured, designed, sold, distributed, supplied and/or placed in the stream of commerce by Defendants, was defective in its manufacture and construction when it left the hands of Defendants in that it deviated from product specifications and/or applicable federal requirements for these medical devices, posing a serious risk of injury and death.

72. As a direct and proximate result of the Plaintiff's use of Defendants' ASR XL Acetabular System, as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants and/or theie failure to comply with federal requirements, the Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer

such harm, damages and economic loss in the future. The Plaintiff suffered severe pecuniary loss. The Plaintiff seeks actual and punitive damages from the Defendants as alleged herein. The injuries and damages alleged herein are permanent and will continue into the future.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

SECOND CAUSE OF ACTION AS AGAINST DEFENDANTS
(STRICT PRODUCTS LIABILITY – DESIGN DEFECT)

73. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows.

74. Defendants are the manufacturers, designers, distributors, sellers, and/or suppliers of orthopedic devices including the DePuy ASR XL Acetabular System.

75. The DePuy ASR XL Acetabular System, manufactured and supplied by Defendants was defective in design or formulation in that, when it left the hands of the Defendants, the foreseeable risks of the product exceeded the benefits associated with its design or formulation, or it was more dangerous than an ordinary consumer would expect, and/or it failed to comply with federal requirements for these medical devices.

76. The foreseeable risks associated with the design or formulation of the DePuy ASR XL Acetabular System, include, but are not limited to, the fact that the design or formulation of the ASR XL Acetabular System is more dangerous than a reasonably prudent consumer would expect when used in an intended or reasonably foreseeable manner, and/or it failed to comply with federal requirements.

77. As a direct and proximate result of the Plaintiff's use of the DePuy ASR XL Acetabular System, as manufactured, designed, sold, supplied, marketed and introduced into the

stream of commerce by Defendants and/or their failure to comply with federal requirements, the Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future. The Plaintiff suffered severe pecuniary loss. The Plaintiff seeks actual and punitive damages from the Defendants as alleged herein. The injuries and damages alleged herein are permanent and will continue into the future.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

THIRD CAUSE OF ACTION AS AGAINST DEFENDANT
(STRICT PRODUCTS LIABILITY – FAILURE TO WARN)

78. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows.

79. The DePuy ASR XL Acetabular System was defective and unreasonably dangerous when it left the possession of the Defendants in that it contained warnings insufficient to alert consumers, including the Plaintiff herein, of the dangerous risks and reactions associated with the ASR XL Acetabular System including but not limited to its propensity to cause component loosening, component mal-alignment, infections, fracture of the bone, dislocation, metal sensitivity and pain, subjecting Plaintiff Donald Paliotti to risks that exceeded the benefits of the ASR XL Acetabular System, including but not limited to the risks of developing serious and dangerous side effects, including but not limited to component loosening, component mal-alignment, infections, fracture of the bone, dislocation, metal sensitivity and pain, irritation and discomfort, as well as the need for additional procedures to remove and replace the ASR XL Acetabular System, as well as other severe and permanent health consequences**,** notwithstanding the Defendants' knowledge of an increased risk of these injuries and side effects over other hip

arthroplasty devices.

80. At the time of the Plaintiff Donald Paliotti's receipt and/or use of the ASR XL Acetabular System, the ASR XL Acetabular System was being used for the purposes and in a manner normally intended, namely for hip arthroplasty.

81. The Plaintiff could not, by the exercise of reasonable care, have discovered the defects herein mentioned and perceived their danger.

82. The Defendants, as manufacturers and/or distributors of the ASR XL Acetabular System, are held to the level of knowledge of experts in the field.

83. The warnings that were given by the Defendants were not accurate, clear and/or were ambiguous.

84. The warnings that were given by the Defendants failed to properly warn physicians of the increased risks, subjecting Plaintiff Donald Paliotti to risks that exceeded the benefits of the ASR XL Acetabular System, including but not limited to the risks of developing serious and dangerous side effects, including but not limited to the risks of developing serious and dangerous side effects, including but not limited to component loosening, component mal-alignment, infections, fracture of the bone, dislocation, metal sensitivity and pain, irritation and discomfort, as well as the need for additional procedures to remove and replace the ASR XL Acetabular System, as well as other severe and permanent health consequences**,** notwithstanding the Defendants' knowledge of an increased risk of these injuries and side effects over other hip arthroplasty devices.

85. Plaintiff Donald Paliotti, individually and through his physicians, reasonably relied upon the skill, superior knowledge and judgment of the Defendants.

86. The Defendants had a continuing duty to warn the Plaintiff of the dangers associated with the ASR XL Acetabular System.

87. Had Plaintiff Donald Paliotti received adequate warnings regarding the risks of the ASR XL Acetabular System, he would not have used it.

88. As a direct and proximate result of the Plaintiff's use of the DePuy ASR XL Acetabular System, and Plaintiff's reliance on Defendants' representations regarding the character and quality of the ASR XL Acetabular System and/or the failure to comply with federal requirements, the Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future. The Plaintiff suffered severe pecuniary loss. The Plaintiff seeks actual and punitive damages from the Defendants as alleged herein. The injuries and damages alleged herein are permanent and will continue into the future.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

FOURTH CAUSE OF ACTION AS AGAINST DEFENDANTS (NEGLIGENCE)

89. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows.

90. Defendants had a duty to exercise reasonable care in the design, manufacture, sale and/or distribution of the ASR XL Acetabular System into the stream of commerce, including a duty to assure that its product did not pose a significantly increased risk of bodily harm and adverse events and/or a duty to comply with federal requirements.

91. Defendants failed to exercise ordinary care in the design, formulation,

manufacture, sale, testing, quality assurance, quality control, labeling, marketing, promotions and distribution of the ASR XL Acetabular System into interstate commerce in that Defendants knew or should have known that the product caused significant bodily harm and was not safe for use by consumers, and/or through their failure to comply with federal requirements.

92. Despite the fact that Defendants knew or should have known that the ASR XL Acetabular System posed a serious risk of bodily harm to consumers, Defendants continued to manufacture and market the ASR XL Acetabular System for use by consumers and/or continued to fail to comply with federal requirements.

93. Defendants knew or should have known that consumers such as the Plaintiff would foreseeably suffer injury as a result of Defendants' failure to exercise ordinary care as described above, including the failure to comply with federal requirements.

94. As a direct and proximate result of Defendants' negligence, the Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future..

95. Defendants' conduct as described above, including but not limited to their failure to adequately design and manufacture, as well as their continued marketing and distribution of the ASR XL Acetabular System when they knew or should have known of the serious health risks it created and/or their failure to comply with federal requirements, evidences a flagrant disregard of human life so as to warrant the imposition of punitive damages. The Plaintiff suffered severe pecuniary loss. The Plaintiff seeks actual and punitive damages from the Defendants as alleged herein. The injuries and damages alleged herein are permanent and will continue into the future.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

FIFTH CAUSE OF ACTION AS AGAINST DEFENDANTS
(BREACH OF EXPRESS WARRANTY)

96. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows.

97. Defendants expressly warranted that the ASR XL Acetabular System was a safe and effective orthopedic device for those patients requiring a hip replacement.

98. The ASR XL Acetabular System manufactured and sold by Defendants did not conform to these express representations because it caused serious injury to the Plaintiff when used as recommended and directed.

99. As a direct and proximate result of Defendants' breach of warranty, the Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

100. Defendants' conduct as described above, including but not limited to their failure to adequately design and manufacture, as well as their continued marketing and distribution of the ASR XL Acetabular System when they knew or should have known of the serious health risks it created and/or their failure to comply with federal requirements, evidences a flagrant disregard of human life so as to warrant the imposition of punitive damages. The Plaintiff suffered severe pecuniary loss. The Plaintiff seeks actual and punitive damages from the Defendants as alleged herein. The injuries and damages alleged herein are permanent and will continue into the future.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

SIXTH CAUSE OF ACTION AS AGAINST DEFENDANTS
(BREACH OF IMPLIED WARRANTY)

101. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows.

102. At the time Defendants designed, manufactured, marketed, sold, and distributed the ASR XL Acetabular System for use by the Plaintiff, Defendants knew of the use for which the ASR XL Acetabular System was intended and impliedly warranted the product to be of merchantable quality and safe for such use and that its design, manufacture, labeling, and marketing complied with all applicable federal requirements.

103. The Plaintiff and/or their physicians reasonably relied upon the skill and judgment of Defendants as to whether the ASR XL Acetabular System was of merchantable quality and safe for its intended use and upon Defendants' implied warranty as to such matters, including that it was in compliance with all federal requirements.

104. Contrary to such implied warranty, the DePuy ASR XL Acetabular System was not of merchantable quality or safe for its intended use, because the product was defective as described above, and/or it failed to comply with federal requirements.

105. As a direct and proximate result of Defendants' breach of warranty, the Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

106. Defendants' conduct as described above, including but not limited to their failure to adequately design and manufacture, as well as their continued marketing and distribution of

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

SEVENTH CAUSE OF ACTION AS AGAINST DEFENDANTS
(NEGLIGENT MISREPRESENTATION)

107. The Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

108. In the exercise of reasonable care, Defendants should have known that their ASR XL Acetabular System failed to comply with federal requirements for safe design and manufacture and/or was in other ways out of specification, yet Defendants negligently misrepresented to the Plaintiff and/or his physicians that its device was safe and met all applicable design and manufacturing requirements.

109. The Plaintiff and/or his physicians reasonably relied to his detriment upon Defendants' misrepresentations and omissions in its labeling, advertisements, and promotions concerning the serious risks posed by these products. The Plaintiff and/or his physicians reasonably relied upon Defendants' representations that the ASR XL Acetabular System was safe for use.

110. As a direct and proximate result of Defendants' negligent misrepresentations and

omissions and/or its failure to disclose its violations of federal requirements applicable to its ASR XL Acetabular System, the Plaintiff used Defendants' ASR XL Acetabular System and the Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future. The Plaintiff suffered severe pecuniary loss. The Plaintiff seeks actual and punitive damages from the Defendants as alleged herein. The injuries and damages alleged herein are permanent and will continue into the future.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

EIGHTH CAUSE OF ACTION AS AGAINST DEFENDANTS
(FRAUDULENT MISREPRESENTATION)

111. Plaintiff incorporates by reference the paragraphs above, as though fully set forth herein.

112. The Defendants falsely and fraudulently represented to the medical and healthcare community and to the Plaintiffs, and/or the FDA, and the public in general, that the subject product had been tested and was found to be safe and/or effective for hip arthroplasty treatment.

113. The representations made by the Defendants were, in fact, false.

114. When said representations were made by the Defendants, they knew those representations to be false and it willfully, wantonly and recklessly disregarded whether the representations were true.

115. These representations were made by the Defendants with the intent of defrauding and deceiving the Plaintiff, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical and healthcare community in particular, to recommend, prescribe, dispense and/or purchase the

subject product for hip arthroplasty treatment, all of which evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of the Plaintiff and the public in general.

116. At the time the aforesaid representations were made by the Defendants and, at the time the Plaintiff Donald Paliotti was treated with the ASR XL Acetabular System, the Plaintiffs were unaware of the falsity of said representations and reasonably believed them to be true.

117. In reliance upon said representations, the Plaintiff Donald Paliotti was induced to, and did use the subject product, thereby sustaining severe and permanent personal injuries including but not limited to significant pain, clicking and popping sensation resulting in revision of defective medical device, irritation and discomfort, as well as other severe and permanent health consequences**,** notwithstanding the Defendants' knowledge of an increased risk of these injuries and side effects over other hip arthroplasty devices.

118. Defendants knew and was aware or should have been aware that the ASR XL Acetabular System had not been sufficiently tested, was defective in nature, and/or that it lacked adequate and/or sufficient warnings.

119. The Defendants knew or should have known that the ASR XL Acetabular System had a potential to, could, and would cause severe and grievous injury to the users of said product, and that it was inherently dangerous in a manner that exceeded any purported, inaccurate, and/or downplayed warnings.

120. The Defendants brought the subject product to the market, and acted fraudulently, wantonly and maliciously to the detriment of the Plaintiff.

121. As a direct and proximate result of Defendants' fraudulent misrepresentations and omissions and/or its failure to disclose its violations of federal requirements applicable to its ASR XL Acetabular System, the Plaintiff used Defendants' ASR XL Acetabular System and the

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

NINTH CAUSE OF ACTION AS AGAINST DEFENDANTS
(FRAUDULENT CONCEALMENT)

122. Plaintiff incorporates by reference the paragraphs above, as though fully set forth herein.

123. At all times during the course of dealing between the Defendants, the Plaintiff, Plaintiff Donald Paliotti's healthcare providers, and/or the FDA, the Defendants misrepresented the safety of the subject product for its intended use.

124. The Defendants knew or was reckless in not knowing that its representations were false.

125. In representations to the Plaintiff, Plaintiff Donald Paliotti's healthcare providers, and/or the FDA, the Defendants fraudulently concealed and intentionally omitted material information, including but not limited to, the fact that:

a. the subject product was not as safe as other similar medical devices indicated for hip arthroplasty;

b. that the subject product was defective, and that it caused dangerous side effects, including but not limited to the risks of developing serious and dangerous side effects, including but not limited to the risks of developing serious and dangerous

side effects, including but not limited to component loosening, component mal-alignment, infections, fracture of the bone, dislocation, metal sensitivity and pain, irritation and discomfort, as well as the need for additional procedures to remove and replace the ASR XL Acetabular System, as well as other severe and permanent health consequences**,** notwithstanding the Defendants' knowledge of an increased risk of these injuries and side effects over other hip arthroplasty devices.

c. that the subject product was manufactured negligently;

d. that the subject product was manufactured defectively;

e. that the subject product was manufactured improperly;

f. that the subject product was designed negligently;

g. that the subject product was designed defectively; and

h. that the subject product was designed improperly.

126. The Defendants were under a duty to disclose to the Plaintiff, Plaintiff Donald Paliotti's healthcare providers, and/or the FDA the defective nature of the subject product, including but not limited to the risk of developing significant pain, irritation and discomfort associated with the use of the ASR XL Acetabular System.

127. The Defendants had sole access to material facts concerning the defective nature of the subject product and its propensity to cause serious and dangerous side effects, and hence, cause damage to persons who used the ASR XL Acetabular System, including the Plaintiff Donald Paliotti, in particular.

128. The Defendants' concealment and omissions of material facts concerning, *inter alia*, the safety of the ASR XL Acetabular System was made purposefully, willfully, wantonly,

and/or recklessly, to mislead the Plaintiff and Plaintiff Donald Paliotti's physicians, hospitals and healthcare providers into reliance on the use of the ASR XL Acetabular System, and to cause them to purchase, prescribe, dispense and/or use the subject product.

129. The Defendants knew that the Plaintiff, Plaintiff Donald Paliotti's healthcare providers, and/or the FDA had no way to determine the truth behind the Defendants' concealment and omissions, as set forth herein.

130. Plaintiff, as well as Plaintiff Donald Paliotti's doctors, healthcare providers, and/or hospitals, reasonably relied on facts revealed which negligently, fraudulently and/or purposefully did not include facts that were concealed and/or omitted by the Defendants.

131. As a direct and proximate result of Defendants' fraudulent misrepresentations and omissions and/or its failure to disclose its violations of federal requirements applicable to its ASR XL Acetabular System, the Plaintiff used Defendants' ASR XL Acetabular System and the Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future. The Plaintiff suffered severe pecuniary loss. The Plaintiff seeks actual and punitive damages from the Defendants as alleged herein. The injuries and damages alleged herein are permanent and will continue into the future.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

TENTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS (FRAUD AND DECEIT)

132. Plaintiff incorporates by reference the paragraphs above, as though fully set forth herein.

133. Defendants conducted research and used the ASR XL Acetabular System as part of their research.

134. As a result of Defendants' research and testing, or lack thereof, Defendants blatantly and intentionally distributed false information, including but not limited to assuring the public, the Plaintiff, his doctors, hospitals, healthcare professionals, and/or the FDA that the ASR XL Acetabular System was safe and effective for use as a means of providing hip arthroplasty treatment.

135. As a result of Defendants' research and testing, or lack thereof, Defendants intentionally omitted certain results of testing and research to the public, healthcare professionals, and/or the FDA, including the Plaintiff.

136. Defendants had a duty when disseminating information to the public to disseminate truthful information and a parallel duty not to deceive the public and the Plaintiff, as well as their respective healthcare providers and/or the FDA.

137. The information distributed to the public, the FDA, and the Plaintiff by Defendants, including but not limited to reports, press releases, advertising campaigns, television commercials, print ads, magazine ads, billboards, and all other commercial media contained material representations of fact and/or omissions.

138. The information distributed to the public, the FDA, and the Plaintiff by Defendants intentionally included representations that Defendants' ASR XL Acetabular System was safe and effective for use as a form of hip arthroplasty treatment.

139. The information distributed to the public, the FDA, and the Plaintiff, by Defendants intentionally included representations that Defendants' ASR XL Acetabular System carried the same risks, hazards, and/or dangers as other forms of hip arthroplasty treatment.

140. The information distributed to the public, the FDA, and the Plaintiff, by Defendants intentionally included false representations that the ASR XL Acetabular System was not injurious to the health and/or safety of its intended users.

141. These representations were all false and misleading.

142. Upon information and belief, Defendants intentionally suppressed, ignored and disregarded test results not favorable to the Defendants, and results that demonstrated that the ASR XL Acetabular System was not safe as a means for treating hip arthroplasty and/or was not as safe as other means of hip arthroplasty treatment, including but not limited to other forms of hip arthroplasty treatment.

143. Defendants intentionally made material representations to the FDA and the public in general, including the medical profession, and the Plaintiff, regarding the safety of the ASR XL Acetabular System, specifically but not limited to ASR XL Acetabular System being as safe a means of hip arthroplasty treatment as other forms of hip arthroplasty treatment.

144. That it was the purpose of Defendants in making these representations to deceive and defraud the public, the FDA, and/or the Plaintiff, to gain the confidence of the public, healthcare professionals, the FDA, and/or the Plaintiff, to falsely ensure the quality and fitness for use of the ASR XL Acetabular System and induce the public, and/or the Plaintiff to have the ASR XL Acetabular System implanted.

145. Defendants made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or the Plaintiff that the ASR XL Acetabular System was fit and safe for hip arthroplasty treatment.

146. Defendants made the aforementioned false claims and false representations with the intent of convincing the public, healthcare professionals, the FDA, and/or the Plaintiff that

the ASR XL Acetabular System was fit and safe for use as hip arthroplasty treatment and did not pose risks, dangers, or hazards above and beyond those identified and/or associated with other forms of hip implant devices.

147. That Defendants made claims and representations in its documents submitted to the FDA, to the public, to healthcare professionals, and the Plaintiff that the ASR XL Acetabular System did not present serious health and/or safety risks.

148. That Defendants made claims and representations in its documents submitted to the FDA, to the public, to healthcare professionals, and the Plaintiff that the ASR XL Acetabular System did not present health and/or safety risks greater than other hip arthroplasty treatment devices.

149. That these representations and others made by Defendants were false when made, and/or were made with a pretense of actual knowledge when knowledge did not actually exist, and/or were made recklessly and without regard to the actual facts.

150. That these representations and others, made by Defendants, were made with the intention of deceiving and defrauding the Plaintiff, including his respective healthcare professionals and/or the FDA, and were made in order to induce the Plaintiff and/or his respective healthcare professionals to rely upon misrepresentations and caused the Plaintiff to have the ASR XL Acetabular System implanted.

151. That Defendants, recklessly and intentionally falsely represented the dangerous and serious health and/or safety concerns of the ASR XL Acetabular System to the public at large, the Plaintiff in particular, for the purpose of influencing the marketing of a product known to be dangerous and defective and/or not as safe as other alternatives, including other forms of hip arthroplasty treatment devices.

152. That Defendants willfully and intentionally failed to disclose the material facts regarding the dangerous and serious safety concerns of the ASR XL Acetabular System by concealing and suppressing material facts regarding the dangerous and serious health and/or safety concerns of the ASR XL Acetabular System.

153. That Defendants willfully and intentionally failed to disclose the truth, failed to disclose material facts and made false representations with the purpose and design of deceiving and lulling the Plaintiff, as well as his respective healthcare professionals into a sense of security so that the Plaintiff would rely on the representations and use of and rely on the ASR XL Acetabular System and/or that their respective healthcare providers would use and/or recommend the same.

154. Defendants, through their public relations efforts, which included but were not limited to the public statements and press releases, knew or should have known that the public, including the Plaintiff, as well as his respective healthcare professionals would rely upon the information being disseminated.

155. Defendants utilized direct to consumer advertising to market, promote, and/or advertise the ASR XL Acetabular System.

156. That the Plaintiff and/or his respective healthcare professionals did in fact rely on and believe the Defendants' representations to be true at the time they were made and relied upon the representations as well as the superior knowledge of hip arthroplasty treatment and were thereby induced to use and rely on Defendants' ASR XL Acetabular System.

157. That at the time the representations were made, the Plaintiff and/or his respective healthcare providers did not know the truth with regard to the dangerous and serious health and/or safety concerns of the ASR XL Acetabular System.

158. That the Plaintiff did not discover the true facts with respect to the dangerous and serious health and/or safety concerns, and the false representations of Defendants, nor could the Plaintiff, with reasonable diligence, have discovered the true facts.

159. That had the Plaintiff known the true facts with respect to the dangerous and serious health and/or safety concerns of the ASR XL Acetabular System, the Plaintiff would not have had the ASR XL Acetabular System implanted.

160. That the Defendants' aforementioned conduct constitutes fraud and deceit, and was committed and/or perpetrated willfully, wantonly and/or purposefully on the Plaintiff.

161. As a direct and proximate result of Defendants' fraudulent misrepresentations and omissions and/or its failure to disclose its violations of federal requirements applicable to its ASR XL Acetabular System, the Plaintiff used Defendants' ASR XL Acetabular System and the Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future. The Plaintiff suffered severe pecuniary loss. The Plaintiff seeks actual and punitive damages from the Defendants as alleged herein. The injuries and damages alleged herein are permanent and will continue into the future.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

ELEVENTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS
(VIOLATION OF VIRGINIA CONSUMER PROTECTION ACT
Va. Code. Ann. 59.1-196 *et seq.*)

162. Plaintiff incorporates by reference the paragraphs above, as though fully set forth herein.

163. The ASR XL Acetabular System is considered "goods" as that term is defined by Va. Code. Ann. 59.1-198. Defendants are designers, manufacturers, promoters, marketers, developers, sellers and/or distributors of the ASR XL Acetabular System.

164. Defendants knew or should have known that the ASR XL Acetabular System was unreasonably dangerous and defective and had a propensity to cause serious and potentially life-threatening side effects. Notwithstanding the foregoing, Defendants omitted material facts concerning the use and safety of the ASR XL Acetabular System in the disclosures it made to the public, the medical community and consumers, including the Plaintiff.

165. Defendants have violated the Virginia Consumer Protection Act, Va. Code. Ann. 59.1-196 *et seq.* Defendants used deception, fraud, false promise, misrepresentation, and/or unfair practices in their packaging, labeling, distributing, marketing, promoting and selling of the ASR XL Acetabular System in the Commonwealth of Virginia. Defendants concealed, suppressed, and/or omitted material facts about the safety of the ASR XL Acetabular System in connection with its sale and/or advertisement in the Commonwealth of Virginia.

166. Defendants' practice of promoting the ASR XL Acetabular System created and/or reinforced a false impression as to its safety and placed all the ASR XL Acetabular System users at risk for serious injury and potentially lethal side effects. Defendants' statements and omissions were made with the intent that the Plaintiff and his prescribing physician would rely on such statements and omissions.

167. The Plaintiff had the ASR XL Acetabular System implanted and suffered an ascertainable loss of money as a result of Defendants' use or employment of the unlawful methods, acts or practices alleged herein.

168. As a direct and proximate result of Defendants' unlawful practices alleged herein, the Plaintiff has suffered ascertainable loss, *i.e.* economic loss that includes the cost of having the ASR XL Acetabular System implanted and additional out-of-pocket healthcare related costs, for which Defendants are liable to Plaintiff.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

TWELVTH CAUSE OF ACTION AS AGAINST THE DEFENDANTS
(PUNITIVE DAMAGES)

169. At all times material hereto, the Defendants knew or should have known that their ASR XL Acetabular System was inherently more dangerous with respect to the risk of significant pain, irritation, discomfort and need for additional surgeries than the alternative hip arthroplasty systems on the market.

170. At all times material hereto, the Defendants attempted to misrepresent and did misrepresent facts concerning the safety of the subject product.

171. Defendants' misrepresentations included knowingly withholding material information from the medical community and the public, including the Plaintiff herein, concerning the safety and efficacy of the subject product.

172. At all times material hereto, the Defendants knew and recklessly disregarded the fact that the ASR XL Acetabular System was subject to an increased risk of causing significant pain, irritation, discomfort and need for additional surgeries in persons implanted with the device with far greater frequency than safer alternative hip arthroplasty systems.

173. Notwithstanding the foregoing, the Defendants continued to aggressively market the subject product without disclosing the aforesaid side effects when there were safer alternative methods.

174. The Defendants knew of the subject product's defective and unreasonably dangerous nature, as set forth herein, but continued to design, develop, manufacture, market, distribute and sell it so as to maximize sales and profits at the expense of the health and safety of the public, including the Plaintiff herein, in conscious and/or negligent disregard of the foreseeable harm.

175. The Defendants' intentional and/or reckless, fraudulent and malicious failure to disclose information deprived the Plaintiff and his surgeon of necessary information to enable them to weigh the true risks of using the subject product against its benefits.

176. As a direct and proximate result of the Defendants' conscious and deliberate disregard for the rights and safety of consumers such as the Plaintiff, the Plaintiff suffered severe and permanent physical injuries as set forth above.

177. The aforesaid conduct of Defendants was committed with knowing, conscious, and deliberate disregard for the rights and safety of consumers, including the Plaintiff herein, thereby entitling the Plaintiff to punitive damages in an amount appropriate to punish the Defendants and deter them from similar conduct in the future.

178. The Plaintiff seeks actual and punitive damages from the Defendants as alleged herein.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray demands judgment against Defendants as follows:

a. Awarding Plaintiffs actual damages incidental to Plaintiff Donald Paliotti's use of the ASR XL Acetabular System in an amount to be determined at trial;

b. Awarding treble and/or punitive damages to the Plaintiff;

c. Awarding pre-judgment and post-judgment interest to the Plaintiff;

d. Awarding the costs and expenses of this litigation to the Plaintiff;

e. Awarding reasonable attorneys' fees and costs to the Plaintiff as provided by law; and

f. Granting all such other, further and/or different relief as the Court may deem just and proper.

Dated: January 2011

Respectfully submitted,

PARKER WAICHMAN ALONSO LLP

By: ____s/Melanie H. Muhlstock ____

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DEMAND FOR JURY TRIAL

Demand is hereby made for a trial by jury.

Date: January 2011

Respectfully submitted,

PARKER WAICHMAN ALONSO LLP

By: s/Melanie H. Muhlstock

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